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REMARKS

After entry of the foregoing amendments, Claims 1-9, 11-15, 22-23, 31-35, 38-42, 44-52, and 67-70 are presented for examination. By the foregoing amendments, Claims 16-21, 24-30, 43, and 53-66 are cancelled without prejudice as non-elected claims pursuant to the previously sent restriction requirement. Also, Claims 10 and 36-37 are cancelled without prejudice. New Claims 67-70 have been added as set forth above. Claims 1-3, 5, 11, 14, 22-23, 31-35, and 44 have been amended as set forth above. Claims 1, 11, 12, 22, 31, 34, 35, and 44 have been amended to further clarify that the systems and methods are capable of distributing products by techniques such as, for example, dispensing, releasing or granting access to the products. The new claims and the amended claims are supported by the specification and the claims as originally filed. Therefore, no new matter has been added. The specific changes to the amended claims are shown above with the insertions being underlined and the ~~deletions shown stricken through.~~

Rejections Under 35 U.S.C. §102

In the Office Action Claims 1-15, 22-23, 31-42 and 44-52 were rejected under 35 U.S.C. §102(b) as being anticipated by Liff et al. ("Liff") (U.S. Patent No. 6,068,156). The pending claims are not anticipated or made obvious by Liff because Liff does not disclose or make obvious each and every element of the claims.

In general, Liff is directed to a drug dispensing system and methods for filling patient prescriptions. However, Liff does not disclose each and every element of each of independent Claims 1, 22, 31, 35, and 44.

Claim 1

Liff does not disclose each and every element of amended Claim 1. Claim 1 as amended includes a sample management subsystem that is similar to the sample management subsystem recited in cancelled Claim 10.

Liff fails to disclose or suggest the distribution of sample medications and certainly does not disclose a sample management subsystem, including the subsystem of Claim 1. As set forth in the application, sample medications are different from prescription medications in their packaging, length of therapy and the exclusion of pharmacist review. *See* specification at

paragraph 0006. A "sample" medication is a legend item (*e.g.*, requires a physician order) packaged by a pharmaceutical company in small quantities and distributed without charge. *See id.* at paragraph 0148. Sample medication distribution typically complies with particular regulations. *See e.g., id.* at paragraph 0007. Again, Liff does not mention sample medications, and not surprisingly, does not disclose a subsystem designed for the unique aspects of sample management.

The sample management subsystem of amended Claim 1 is coupled to the one or more dispensers and configured to track the distribution of a sample medication to a patient, to initiate a determination of whether the medication is appropriate for the patient, and to send a control signal to the one or more dispenser units to distribute a sample medication. No such system in combination with the other elements of Claims 1 is taught or suggested by Liff.

Furthermore, one aspect of Claim 1 relates to a medical system that includes, *inter alia*, a prescription subsystem *and* a sample management subsystem. As detailed above, sample medications are different from prescription medications and Liff does not disclose a system with a prescription subsystem in combination with a sample management subsystem.

In rejecting now cancelled Claim 10, the Office Action stated that Liff disclosed a sample management subsystem as demonstrated by Figures 7B, 7C and 8 from Liff. However, none of Figures 7B, 7C or 8 describes a sample management subsystem as recited in amended Claim 1 or the combination of a prescription subsystem and a sample management subsystem together.

Figures 7B and 7C describe flow diagrams for only a *prescription* submenu. *See* Liff column 3, lines 49-50 and column 12, lines 14-45. However, as discussed above, prescription medications are different from sample medications and Liff does not even suggest using the submenu of Figures 7B and 7C for sample management alone. Furthermore, Figures 7B and 7C do not disclose a system that includes *both* a prescription subsystem and a sample management subsystem together.

In addition, Liff described Figure 8 as a schematic diagram illustrating the administration of a clinical trial. *See id.* at column 3, lines 51-52 and column 13, lines 52-62. However, Figure 8 discloses a system limited to controlled dispensing of clinical trial medication. Figure 8 does not disclose or even suggest a system with both a prescription subsystem and a sample management subsystem as set forth in amended Claim 1.

For the reasons set forth above, Liff does not disclose or suggest the system of Claim 1. Therefore, amended Claim 1 and its dependent claims are not anticipated by Liff.

Claim 22

Liff does not teach each and every element of amended Claim 22. Claim 22 also has been amended to include, *inter alia*, a sample management subsystem similar to the sample management subsystem of cancelled Claim 10.

The medication dispenser of amended Claim 22 includes, *inter alia*, a prescription subsystem in combination with a sample management subsystem. As was discussed above, nowhere does Liff specifically discuss distributing sample medication individually, and Liff certainly does not disclose a medication dispenser with a subsystem for prescription medication in combination with a subsystem for sample medications.

Liff disclosed a system for the dispensing of prescription medications. However, the system of Liff does not disclose or even suggest a sample management subsystem as set forth in amended Claim 22. For example, the system of Liff certainly does not track the distribution of sample medications to patients, and does not initiate the transmission of sample medication distribution data as set forth in amended Claim 22.

For the reasons discussed above, amended Claim 22 and its dependent Claim 23 are not anticipated by Liff.

Claim 31

Liff does not teach each and every element of amended Claim 31.

One aspect of amended Claim 31 relates to a marketing module. The marketing module of amended Claim 31 is similar to the marketing subsystem of pending Claim 23. Liff does not disclose the claimed combination that includes, *inter alia*, a prescription module and a marketing module. We are unable to find in Liff any recognition of the need for marketing, and Liff certainly does not disclose a marketing module. Liff also does not suggest including marketing in its system.

The claimed marketing module provides data regarding product usage and receives marketing information in response to that product usage data. Liff does not disclose a marketing

module as part of its system and certainly does not include a module that provides data regarding product usage and that receives marketing information in response to that product usage data.

Therefore, Liff does not anticipate amended Claim 31 or any claims depending therefrom.

Claim 35

Liff does not teach each and every element of independent Claim 35.

Amended Claim 35 is directed to a system which includes, *inter alia*, an inventory management module configured to control and manage the physical inventory and virtual inventory of the product. The inventory management module is similar to the inventory management module of cancelled Claims 36-37. In discussing the rejection of claims directed to related inventory management systems and modules, the Office Action stated that virtual and actual inventories are functionally equivalent to each other and that access is controlled according to ownership of the medication. *See* Office Action at pages 3-4, paragraphs 6-7.

Systems for managing both types of inventories are not functionally equivalent, and Liff does not disclose an inventory management module configured to control and manage the physical inventory and virtual inventory of the product. In many medical settings there are conditions in which individual parties operate together in a common physical space. *See for example,* specification at page 48, paragraph 0226 bridging page 49, paragraph 0231. It may be necessary in those settings to separate the ownership, accounting and management of separately owned product that is stored in the same storage device. *See id.* It also may be necessary to control and manage the access to such individually owned and co-mingled product.

As a hypothetical example, a particular medical office may have two doctors, Dr. A and Dr. B., that share the same dispensing unit. The dispensing unit may store together, for example, Dr. A's 10 packages of drug X and Dr. B's 20 packages of drug X, for a total of 30 packages of drug X. Thus, the physical inventory of the dispensing unit shared by A and B would be 30 packages of drug X. The virtual inventory of drug X for each doctor would be Dr. A, 10 packages and Dr. B, 20 packages. Virtual inventory manages this situation by controlling access of each doctor to the 30 packages of drug X according to the individual virtual inventory count for each. For example, once Dr. A has dispensed his entire virtual inventory of 10 packages of drug X, he might not be permitted to dispense additional packages of drug X because the additional packages belong to Dr. B.

Liff may disclose monitoring of a physical inventory; however, Liff does not disclose an inventory management module that controls and manages a virtual inventory, that is one that tracks ownership and dispensing of a plurality of individually owned and co-mingled product inventories located in one or more dispensers. Liff does not address such situations where, for example, a product owned by one doctor is stored together with and distributed from the same device as a product owned by a second doctor.

Therefore Liff does not anticipate Claim 35 or the claims depending therefrom because Liff does not teach each and every element of Claim 35.

Claim 44

Finally, Liff does not teach each and every element of independent Claim 44.

Claim 44 relates to a medical system that includes, *inter alia*, a prescription subsystem in combination with a sample management subsystem and an over-the-counter subsystem. The sample management subsystem of Claim 44 is similar to the sample management subsystem of cancelled Claim 10, and the over-the-counter subsystem of Claim 44 is similar to the over-the-counter subsystem of Claim 12.

Liff disclosed a system designed to dispense one type of medication, namely prescription medications. Nowhere does Liff discuss distributing sample medication individually or over-the-counter medication individually, and Liff certainly does not disclose a system with a subsystem that distributes prescription medication in combination with a subsystem that distributes a sample medication in combination with a subsystem that distributes over-the-counter medication.

Furthermore, as set forth above, a sample medication is different from a prescription medication. Similarly, an over-the-counter medication is different from a sample medication and from a prescription medication. An over-the-counter medication, also known as a non-legend item, is one that can be purchased or distributed without a prescription. *See* page 23, paragraph 0128. These different products are subject to different regulations and distribution requirements. Respectfully, the assertion in the Office Action is incorrect that such products will be handled in substantially the same fashion, using the same equipment and structure.

Liff does not disclose individual subsystems or the combination as recited in amended Claim 44. Therefore, Claim 44 and its dependent claims are not anticipated by Liff because Liff fails to disclose each and every element of independent Claim 44.

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Therefore, for the reasons set forth above, Applicants respectfully request withdrawal of the rejections under 35 U.S.C. §102(b) and allowance of the pending claims.

CONCLUSION

Applicants have endeavored to address all of the Examiner's concerns as expressed in the outstanding Office Action. Accordingly, amendments to the claims, the reasons therefor, and arguments in support of the patentability of the pending claim set are presented above. Any claim amendments which are not specifically discussed in the above remarks are made in order to improve the cosmetics of the claims. In light of the above amendments and remarks, reconsideration and withdrawal of the outstanding rejections is specifically requested. If the Examiner finds any remaining impediment to the prompt allowance of the pending claims, the same is invited to contact the undersigned.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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Dated: 6/9/03

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